K053565

SYBRON DENTAL SPECIALTIES

FEB 3 2006

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
100 Bayview Circle, Suite 6000
Newport Beach, California 92660
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Colleen Boswell - Contact Person

Date Summary Prepared: December 2005

Device Name:

- Trade Name – *TempBond Clear with Triclosan*
- Common Name – Temporary Dental Cement
- Classification Name – Dental Cement – other than zinc oxide-eugenol, per 21 CFR § 872.3275 (b)

Devices for Which Substantial Equivalence is Claimed:

- Kerr Corporation, *TempBond Clear*

Device Description:

TempBond Clear with Triclosan is a dual-cured, temporary, eugenol-free, resin-based cement with triclosan. This base/catalyst cement is flexible and transparent when cured. The device will be packaged in a dual-barrel syringe to eliminate hand mixing. It has excellent flow to permit the restoration to be easily and completely seated. It is strong enough to withstand the stresses of mastication, yet permits easy removal of the restoration when it is desired. *TempBond Clear with Triclosan* contains triclosan.

Intended Use of the Device:

The intended use of *TempBond Clear with Triclosan* is for the temporary cementation of temporary restorations such as crowns, bridges, inlays, onlays and splints.

Substantial Equivalence:

TempBond Clear with Triclosan is substantially equivalent to other legally marketed devices in the United States. This temporary dental cement which will be manufactured by Kerr Corporation functions in a manner similar to and is intended for the same use as the product currently marketed by Kerr.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2006

Ms. Colleen Boswell
Director, Corporate Compliance
Sybron Dental Specialties, Incorporated
100 Bayview Circle, Suite 6000
Newport Beach, Califorina 92660

Re: K053565
Trade/Device Name: TempBond Clear with Triclosan
Regulation Number: 21 CFR 872.3275(b)
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: December 21, 2005
Received: December 22, 2005

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053565

Device Name: *TempBond Clear with Triclosan*

Indications For Use:

TempBond Clear with Triclosan is a dual-cured, temporary, eugenol-free, transparent, resin-based cement with triclosan designed to be used in conjunction with temporary restorations such as crowns, bridges, inlays, onlays and splints.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K053565